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§12–510.

- (a) Except as provided in subsection (b) of this section, a pharmacist may provide compounded nonsterile preparations or compounded sterile preparations without a patient—specific prescription to a licensed veterinarian who intends to dispense the compounded nonsterile preparations or compounded sterile preparations in accordance with § 2–313(c) of the Agriculture Article if the pharmacist:
  - (1) Complies with USP 795 or USP 797, as applicable;
- (2) Labels the compounded nonsterile preparations or compounded sterile preparations with:
- (i) The name and strength of the compounded nonsterile preparations or compounded sterile preparations or a list of the active ingredients and the strength of the active ingredients in the compounded nonsterile preparations or compounded sterile preparations;
- (ii) An appropriate beyond—use date as determined by the pharmacist in accordance with USP—NF standards for pharmacy compounding;
- (iii) The quantity of compounded nonsterile preparations or compounded sterile preparations; and
- (iv) The name, address, and license number of the pharmacy; and
  - (3) Complies with applicable federal law and regulations.
- (b) (1) This subsection does not apply to dispensing compounded nonsterile preparations or compounded sterile preparations dispensed for a patient–specific prescription.
- (2) A pharmacy may not provide compounded nonsterile preparations or compounded sterile preparations compounded using bulk drug substances to a licensed veterinarian:
- (i) In an amount greater than 10% of the total amount of drug products sold or dispensed from the pharmacy; or

- (ii) If the compounded nonsterile preparations or compounded sterile preparations are copies or close approximations to products approved by the federal Food and Drug Administration.
- (3) For purposes of the limitation established in paragraph (2)(i) of this subsection:
- (i) The calculation shall be made on an annual basis and use the number of dosage units sold or dispensed; and
- (ii) For nonresident pharmacies, the total amount of drug products sold or dispensed shall be the pharmacy's total business within the State.

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